Layperson's abstract (250-400 words)

Our group of physicians and scientists are interested in researching an exciting new modality of treatment available for patients with Coronary Artery Disease and Peripheral Vascular Disease. This involves the process of growing new blood vessels, referred to as "angiogenesis". The last decade or so have seen the emergence of numerous growth factors that are capable of inducing the growth of new blood vessels. The process of angiogenesis provides a new strategy for dealing with the consequences of atherosclerosis, which is the most prevalent cause of blood vessel narrowing be it in the heart (in patients with coronary artery disease) or in the arteries of the lower leg (in patients with peripheral vascular disease). The formation of new blood vessels provides a biologic bypass mechanism of improving blood flow. This may serve as a useful adjunctive therapy for traditional approaches such as angioplasty or surgical bypasses in the near future. One such angiogenic factor is Vascular Endothelial Growth Factor (VEGF). The administration of VEGF protein in several animal models and in humans with peripheral vascular disease has been shown to induce the growth of new blood vessels. An obvious clinical strategy would be the administration of VEGF itself in conditions requiring the generation of new blood vessels. However this would require large quantities of the compound that would have to be continuously administered. Generation of such large quantities of protein for human application is currently not feasible. An alternate approach involves the induction of the angiogenic response through gene therapy, by delivering the gene for VEGF to the patient. In the proposed research protocol which is part of a multi-center clinical trial, the safety and efficacy of AdVEGF121.10 will be examined in patients with peripheral vascular disease, a condition associated with atherosclerosis (narrowing of the arteries) of the lower extremities, and reduced blood flow. Participants are randomized into treatment groups (either drug therapy or placebo [inactive drug]) by a computer so that the investigator and the patient do not know what group they are placed in. The success of this treatment is measured by improvement on the treadmill testing that is done at baseline and after treatment. Other measures of successful growth of new arteries are changes in amount of pain you fell when you walk , changes in perfusion (blood flow) and hemodynamic effects (change in flow before and after exercise) and changes in the questionnaires that you answer.